JUN 6 2002

K021010

Endocare, Inc.
Special 510(k): Modified Cryocare Cardiac Surgical System

Attachment 5

endocare

Prepared March 28, 2002

TRADE NAME	**Modified Cryocare Cardiac Surgical System**		
CLASSIFICATION	**Class II (21 CFR 878.4350)**		
SUBMITTED BY	Endocare, Inc. 7 Studebaker Irvine, CA 92618	**CONTACT**	Eben Gordon Regulatory Affairs (949) 595 5424
PREDICATE DEVICE	K011040 - Endocare Cryocare Cardiac Surgical System. Decision date: 06/15/2001		
DEVICE DESCRIPTION	The modified Cryocare Cardiac Surgical system consists of a control unit that operates one single use, disposable cryoprobe. The control unit is software controlled and operates off standard 120/230 VAC wall power. System control is accomplished directly through keys on the console itself. The Cryoprobes operate on the Joule-Thompson principle and the refrigerative capacity is limited to the freeze zone of the probe. The cryoprobe incorporates a thermocouple to measure temperature at the probe tip. The thermocouple is mounted inside the cryoprobe tip and its signal is used to monitor some operations of the system. The temperature probe is a standard T-type needle thermocouple.		
INDICATIONS FOR USE	The Cryocare Cardiac Surgical System is indicated for use in minimally invasive cardiac surgery procedures, including surgical treatment of cardiac arrhythmias. The Cryocare Cardiac Surgical Probes freeze the target tissue and block the electrical conduction pathway by creating an inflammatory response or cryonecrosis		
TESTING	In-vitro performance testing of the Endocare Modified Cryocare Cardiac Surgical System included dimensional inspection, flex tests, endurance tests, burst pressure tests, performance under simulated use conditions. All testing of the product yielded acceptable results.		
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The Endocare Modified Cryocare Cardiac Surgical System is substantially equivalent to the predicate device in intended use and principles of operation.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2003

Endocare, Inc.
c/o Mr. Eben Gordon
Director, Regulatory Affairs
7 Studebaker
Irvine, CA 92618

Re: K021010
Trade/Device Name: Modified Cryocare Cardiac Surgical System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II (two)
Product Code: OCL
Dated: May 8, 2002
Received: May 10, 2002

Dear Mr. Gordon:

This letter corrects our substantially equivalent letter of June 6, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

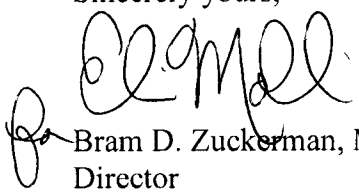
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known): K021010

Device Name: **Modified Cryocare Cardiac Surgical System**

Indications for Use: **The Cryocare Cardiac Surgical System is indicated for use in minimally invasive cardiac surgery procedures, including surgical treatment of cardiac arrhythmias. The Cryocare Cardiac Surgical Probes freeze the target tissue and block the electrical conduction pathway by creating an inflammatory response or cryonecrosis.**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over the Counter Use** _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021010